A-A-50879A
30 August 1991
SUPERSEDING
A-A-50879
28 September 1983

COMMERCIAL ITEM DESCRIPTION

STERILIZATION TEST STRIP SET, BACTERIAL SPORE

The General Services Administration has authorized the use of this Commercial Item Description as a replacement for MIL-S-36586A which is cancelled.

This Commercial Item Description covers a sterilization test strip set for use in determining the efficiency of sterilization by bacteriological culture test.

Salient characteristics:

The sterilization test strip set shall be a biological indicator for use in determining the efficiency of sterilization by bacteriological culture test.

The set shall be an absorptive strip of filter paper not less than 1/4 inch wide by 1-3/8 long, impregnated with populations of bacillus stearothermophilus and bacillus subtilis (globigii or var. niger) viable dry bacterial spores adjusted to give predetermined resistance.

The spore strips shall meet the following conditions of time, method, and temperature:

1. Saturated steam under pressure:

    * Bacillus stearothermophilus - 100 percent survival at 250 deg. F for 5 minutes.
    * Bacillus stearothermophilus - 100 percent kill at 250 deg. F for 15 minutes.
    * Bacillus stearothermophilus - 100 percent survival at 270 deg. F for 20 - 30 seconds.
    * Bacillus stearothermophilus - 100 percent kill at 270 deg. F for 2 - 5 minutes.

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AMSC N/A

2. Dry Heat:

   * Bacillus subtilis - 100 percent kill at 320 deg. - 338 deg. F for 2 - 4 hours.

3. Ethylene Oxide - 600 plus or minus 60 milligrams per liter concentration and relative humidity of 60 plus or minus 20 percent:

   * Bacillus subtilis - 100 percent survival at 130 deg. F for 15 minutes.

   * Bacillus subtilis - 100 percent kill at 130 deg. F for 120 minutes.

4. Ethylene Oxide - 1200 plus or minus 120 milligrams per liter concentration and relative humidity of 60 plus or minus 20 percent:

   * Bacillus subtilis - 100 percent survival at 130 deg. F for 5 minutes.

   * Bacillus subtilis - 100 percent kill at 130 deg. F for 30 minutes.

The strips shall be in an individual steam permeable, sterilizable, glassine envelope measuring approximately one inch wide by at least two inches long.

The strips, in the glassine envelopes, shall be assembled into individual test sets, each test set to consist of two test strips and one control strip. Each test set shall be marked with an expiration date. The expiration dating period shall be not less than 18 months. Not more than 3 months of the expiration dating period shall have elapsed at time of delivery to destination.

The set shall meet the requirements of the AAMI Standards for Biological Indicators for Ethylene Oxide and Saturated Steam Sterilization Processes.

Tests shall be performed utilizing AAMI, Standard for Bier/Steam Vessels where appropriate.

Workmanship. The sterilization test strip set shall be free from defects which detract from its appearance or impair its serviceability.

Unit Package (PG). One package containing 25 procedure envelopes, as specified, constitutes one unit.

Quality Assurance Provisions.

Responsibility for inspection. Unless otherwise specified in the contract or purchase order, the contractor is responsible for the performance of all inspection requirements as specified herein. Except as otherwise specified in the contract or purchase order, the contractor may use his own or any facilities suitable for the performance of the inspection requirements specified herein, unless disapproved by the Government. The Government reserves the right to perform any of the inspections set forth in the specification where such inspections are deemed necessary to assure supplies and services conform to prescribed requirements.

Records. Records of examinations and tests performed by or for the contractor shall be maintained by the contractor and made available to the Government upon the Government's request, at any time, or from time to time, during the performance of the contract and for a period of three years after delivery of the supplies to which such records relate.

Inspection. Inspection, as used herein, is defined as both examination (such as visual or auditory investigation without the use of special laboratory appliances or procedures) and testing (determination by technical means of physical and chemical properties) of the item.

Sampling for examination. Sampling for examination shall be conducted in accordance with MIL-STD-105, with an AQL of 2 (percent defective) and an inspection level of II. The unit of product for examination purposes shall be ten sterilization test sets, as specified.

Sampling for tests. Sampling for tests, including dimensional test, shall be conducted in accordance with MIL-STD-105, with an AQL of 2 (percent defective) and an inspection level of II. The unit of product for test purposes shall be ten sterilization test strip sets, as specified.

Tests. Tests shall be conducted to determine compliance with specification requirements and AAMI Standards for Biological Indicators for Ethylene Oxide and Saturated Steam Sterilization Processes. Where feasible, the same sample shall be used for the determination of two or more test characteristics.

Metric products. Products manufactured to metric dimensions will be considered on an equal basis with those manufactured using inch-pound units, providing they fall within the tolerances specified using conversion tables contained in the latest revision of Federal Standard 376, and all other requirements of this document are met.

If a product is manufactured to metric dimensions and those dimensions exceed the tolerances specified in the inch/pound units, a request should be made to the contracting officer to determine if the product is acceptable.

The contracting officer has the option of accepting or rejecting the product.

Contractor certification. The contractor shall certify that the product offered meets the salient characteristics of this description and conforms to the producers' own drawings, specifications, standards, and quality assurance practices. The Government reserves the right to require proof of such conformance prior to first delivery and thereafter as may be otherwise provided for under the provisions of the contract.

Regulatory requirements.

Federal Food, Drug and Cosmetic Act. If the product covered by this document has been determined by the U.S. Food and Drug Administration to be under its jurisdiction, the offeror/contractor shall comply, and be responsible for compliance by its subcontractors/suppliers, with the requirements of the Federal Food, Drug and Cosmetic Act, as amended, and regulations promulgated thereunder. In addition, the offeror/contractor shall comply, and be responsible for compliance by its subcontractors/suppliers, with the requirements of all other applicable Federal, State, and local statutes, ordinances and regulations.

Recovered materials. The offeror/contractor is encouraged to use recovered material in accordance with Federal Acquisition Regulation Subpart 23.4 to the maximum extent practical.

Preservation, packaging, packing, labeling, and marking. Unless otherwise specified, preservation, packaging, and packing shall be to a degree of protection to preclude damage to containers and/or contents thereof under normal shipping conditions, handling, etc., involving shipment from the supply source to the receiving activity, plus reshipment from receiving activity, and shall conform to applicable carrier's rules and regulations. Intermediate and exterior package quantities and labeling and marking shall be as specified in the contract and/or order.

Ordering data. Intermediate/exterior package quantities, labeling, and marking must be specified in the contract and/or order.

NOTE: The following National Stock Number is covered by this document.

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MILITARY INTERESTS:

Custodians:

Army - MD
Navy - MS
Air Force - 03

CIVIL AGENCY COORDINATING ACTIVITIES:

VA-OSS
USPHS
FDA-MPQAS

PREPARING ACTIVITY:

DoD-MB

Agent:

DLA-DM

Project Number: 6530-2052

Location: STER2CID.1BC